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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,950	10/06/2003	Marcel Hunn	33635/US	3584

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Dorsey & Whitney LLP
IP Department, ATTN: Disetronic Licensing AG
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498

EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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01/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/679,950	Applicant(s) HUNN ET AL.	
	Examiner Elizabeth R. MacNeill	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5,8,10,11,13,14,19-21,33,37,54 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5,8,10,11,13,14,19-21,33,37,54 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 October 2007 has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 3,5,8,10,13,14,21 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Bley et al (US 5,762,630).

Bley teaches a cannula (117 and 113) composed a first material (shape memory polymer such as MM-3510, Col 4 at line 50) which is thermally susceptible, and a second material (hub 117).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 33,37,55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwatschenko (US #4,306,563) in view of Bader et al (US 4,835,248).

Regarding claims 33, Iwatschenko teaches "A cannula that increases in pliability during use, wherein the cannula comprises a water-absorbing material (8) of a first variable hardness that decreases in hardness upon water absorption (Col 3 line 8) and a material having a second hardness (plastic)

Iwatschenko does not disclose that the material of a polyamide.

Bader et al discloses a polyamide based coating which dissolves in the body and can be used for catheters (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polyamide coating with the variable hardness catheter of Iwatschenko since "these polymers are metabolized into nontoxic, nonallergenic and nonimmunogenic compounds and are excreted." (Col 1 line 61-64)

Regarding claim 37, the water-absorbing material is the outer material of the cannula, and the material having the second hardness is the inner material of the cannula. As to claims 55 and 56, the tip would be capable of piercing the skin or a septum. Additionally, the hardness of a steel needle is dependent on the shape and size of the needle.

3. Claims 3,5,8,10,11,13,14,19-21, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwatschenko (US #4,306,563) in view of Bley (US 5,762,630)

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Regarding claim 8, Iwatschenko teaches "A cannula (2) which increases in pliability during application, wherein, prior to application, said cannula comprises one a material of a first variable hardness (8) and a second material having a second hardness (2), of which said material having the greater hardness is at least partially dissolved during use." See Col 3 lines 20-25 and Claim 1.

Iwatschenko does not disclose that the material is thermally susceptible.

Bley discloses thermally susceptible polymer which dissolves in the body and can be used for catheters (Col 4 line 50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a thermal coating with the variable hardness catheter of Iwatschenko since such a coating would rapidly soften in the body.

Regarding claim 3, the two materials are a composite (Fig 1)

Regarding claim 5, the composite is a solid-state material (plastic, Col 1 line 9) and an organic polymer (PVA, Col 3 line 10)

Regarding claim 10, the cannula contains a material of lower hardness (2) than the dissolving material (8)

Regarding claim 11, the material of first variable hardness at least partially surrounds the material having a lower initial hardness (Fig 1)

Regarding claim 13, the hardness of the material of lower hardness does not change during use (plastic, Col 1 line 9)

Regarding claim 14, the material of greater hardness surrounds the material of lower hardness (Fig 1)

Regarding claim 19, the PVA is readily water soluble, and meets the limitation of the applicant's specification regarding the preferred materials as disclosed in the specification.

Regarding claim 20, the material having the greater hardness is removed during use (by dissolution)

Regarding claim 21, the materials are separated by layers (Fig 1)

Response to Arguments

4. Applicant's arguments filed 17 October 2007 have been fully considered but they are not persuasive. In response to applicant's arguments, the recitation "exhibits a selected flow cross-section...puncture a septum...formed of at least one material" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The body of the claim begins after "wherein the cannula comprises." Regarding Iwatschenko in view of Bader, applicant argues that the compound is not degradable based on water absorption. See Col 5 line 6 that the compound does absorb water in order to release its active component and later dissolves. Water absorption will decrease the hardness of the material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

